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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,203	09/23/2003	Michael P. Wallace	03-247 (US01)	2638

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EXAMINER	
ROANE, AARON F	

ART UNIT	PAPER NUMBER
3739	

MAIL DATE	DELIVERY MODE
06/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,203	WALLACE, MICHAEL P.	
	Examiner	Art Unit	
	AARON ROANE	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-14,16,18,19,25,26 and 37-42* is/are pending in the application.

4a) Of the above claim(s) *4,9,14,16 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-8,10-13,18,19,25 and 37-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 May 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/4/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6-8, 10-13, 18, 19, 25 and 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ken et al. (USPN 5,853,418) in view Günther et al. (USPN 6,238,421) and in further view of Wallace et al. (USPN 6,280,457) in still further view of Engelson (USPN 6,024,754).

Regarding claims 1, 6, 10, 11, 18, 19, 25, 37 and 39-42 Ken et al. disclose a vaso-occlusive device for treating a site within a patient's vasculature, the device comprising a helically wound coil (coiled formed by 102 and its analogous

counterparts in the other embodiments) forming a lumen and formed of platinum (see col. 4, lines 47-60), a filament/heating member (first material) (108, 208 and 214 and their analogous counterparts in the other embodiments) disposed in the lumen, the heating member at least partially comprising a first highly resistive, ferrous material (contains iron), the first material that is embedded within the device and which may be heated by application of a source of energy external to a patient's body after the device is implanted at a treatment site in the patient's body, see col. 1-9, particularly col. 4, line 6 through col. 5, line 10 and figures 1A-11D. Ken et al. fail to disclose the device may be heated by an energy emitting element external to the patient. Ken et al. also fail to disclose a bioactive agent that is activated or released when the device is heated. Günther et al. disclose an induction heating device and method for metallic implants in the living beings and teach using “a conducting coil and an RF generator are used in the present invention to heat a metallic implant inductively from outside the body” in order to treat aneurysms, see col. 2, line 44 through col. 5, lines 37. Wallace et al. also disclose a vaso-occlusive coil device and teach that “the polymeric fibers covering the device are used as a carrier for bioactive molecules”. Non-limiting examples of bioactive materials which increase cell attachment and/or thrombogenicity include both natural and synthetic compounds, e.g., collagen, fibrinogen, vitronectin, other plasma proteins, growth factors (e.g., vascular endothelial growth factor, "VEGF"), synthetic peptides of these and other proteins

having attached RGD (arginine-glycine-aspartic acid) residues, generally at one or both termini. In addition, polynucleotide sequences encoding peptides (e.g., genes) involved in wound healing or promoting cellular attachment may also be used, see col. 12, lines 3-14. Engelson discloses an aneurysm closure coil device and method and teaches providing the coil device (240) with a "coating of polymeric composition" that upon heating melts and comes off the coil, and once heat is removed the polymeric material "can be coalesced, reformed, or solidified in the vasculature" in order to enhance the treatment of aneurysm, see col. 2, line 66 through col. 3, line 32 and col. 4-10, particularly col. 9, line 25 through col. 10, line 5 and figures 1- 12C, particularly figures 12A-12C. Once the polymeric coating is heated and melts away from or off of the coil (Engelson) the bioactive agent is released (Wallace et al.). Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Ken et al., as taught by Günther et al. et al., to provide heating energy from outside/external source as an alternate means of heating the implantable metallic coil, and as further taught by Wallace et al., to provide the coil with a polymeric coating having a bioactive agent in order to improve the vaso-occlusion treatment, and still as further taught by Engelson, to provide the coil with a polymeric coating that is released from the coil upon heating in order to further enhance the treatment of aneurysms.

Regarding claims 2, 3, 12 and 13, Ken et al. in view Günther et al. and in further view of Wallace et al. and still in further view of Engelson disclose the claimed invention, see the polymeric material coating of Engelson (entire reference).

Regarding claims 7 and 38, Ken et al. in view Günther et al. and in further view of Wallace et al. and still in further view of Engelson disclose the claimed invention.

Regarding claim 8, Ken et al. in view Günther et al. and in further view of Wallace et al. and still in further view of Engelson disclose the claimed invention. It can be clearly seen that (108 and all analogous counterparts in other embodiments) of Ken et al. is embedded in the element, see figures 1A-10.

Regarding claim 30, Ken et al. in view Günther et al. and in further view of Wallace et al. and still in further view of Engelson disclose the claimed invention.

Regarding claim 34, Ken et al. disclose the claimed invention, see col. 1-9, particularly col. 4, line 6 through col. 5, line 10 and figures 1A-11D.

Response to Arguments

Applicant's arguments filed 4/4/2008 have been fully considered but they are not persuasive. The examiner will address each argument/remark in turn.

Beginning on page 10, the last three lines and continuing to page 11, line 12, Applicant asserts "there is no disclosure or suggestion in Ken that such 'modest amounts of iron' in the stretch-resisting filament are provided in adequate concentration to cause the stretch- resisting filament to act as a heating member if exposed to energy transmitted by external energy emitting element when the coil is detached from a delivery catheter and implanted at a treatment site, as required by independent claims 1, 37 and 42." This argument is not persuasive since iron, any amount, large or small, heats up when exposed to an alternating magnetic field, thus the iron disclosed "acts" as a heating member. Applicant next asserts in the same passage there is no "mention in Ken if the 'optional' modest amounts of iron would be embedded in the filament versus applied as a coating, or otherwise. And, in particular, there is no mention in Ken that the coil itself contains, (or may optionally contain), any amount of iron, despite a very detailed description of what materials the coils are made from at lines 47-60 of column 4 of Ken." This is incorrect since Ken et al. disclose a filament/heating member (first material) (108, 208 and 214 and their analogous counterparts in the other embodiments) disposed in the lumen, the heating member at least partially comprising a

first highly resistive, ferrous material (contains iron), which is very clearly part of the coil device and contains is broadly interpreted as embedded.

Next on page 11, first full paragraph, Applicant asserts:

Gunther discloses an induction heating device outside the body that raises the temperature of living cells that immediately surround a metallic implant in a patient's body causing shrinkage, slowing or stopping cell generation in the body (Col. 3, lines 1-7). As stated in Gunther "the goal of the inductive heating is to raise the temperature of the cells surrounding a stent matrix so that the cells will shrink and cell generation will slow." (Col. 3, lines 41-43).

It appears Applicant has missed a key point of Gunther et al. and that is that the alternating magnetic field is used to inductively heat a magnetic implant, see abstract, col.1-2 and various other passages. Thus it is clear that Gunther et al. teach using applying an alternating magnetic field to a metallic implant to inductively heat the implant.

Next on page 12, lines 5 and 6, Applicant asserts “there is no disclosure in Wallace that the bioactive agent carried by its device of Wallace is released or activated by heat.” Wallce et al. was used to teach the polymerizable material having bioactive agents not necessarily whether or not the bioactive agent is activated/released upon exposure to heat. Further it would appear that Applicant is arguing against the

references individually, and it should be pointed out that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir.1986). The release of the polymerizable material/coating is taught by Engelson. So the mere combination of Wallace et al. and Engelson provides a releasable polymerizable coating containing a bioactive agent.

On page 12, first full paragraph, Applicant asserts "Engelson discloses a light emitting device that 'has been introduced into the region just outside the mouth of the aneurysm' (Col. 8, lines 48-51) in order to reform polymers to adhere to each other and stabilize a vaso-occlusive device. There is no disclosure or suggestion in Engelson that an energy emitting device located outside the body would heat a vaso-occlusive device to release, activate bioactive agents after the device is implanted in the body." Again Engelson teaches the release of the polymerizable material/coating to treat an aneurysm. Additionally, Engelson also teach "polymeric composition is reformed via light, heat, R.F. or the like to form a rigid mass with the solid vaso-occlusive device," see abstract. Again, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant has argued against the rejections based solely on what the individual references disclose and not what the combination of references disclose. The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art, and all teachings in the prior art must be considered to the extent that they are in analogous arts. Additionally, Applicant asserts there is no reason and the action fails to point out any reasoning to combine and/or modify the inventions of the individual references. The examiner can only disagree as the reasoning for the combination is contained in the rejections above and specifically in the statement of obviousness.

Finally, the examiner can not stress enough that Applicant has failed the refute the rejections based on the combination of the prior art and not, as Applicant has done, argued against the individual references. Again, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant should take care to distinguish what Applicant has disclosed in the specification and what is broadly claimed in the present claims particularly with respect to the iron.

This action is made FINAL.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON ROANE whose telephone number is (571)272-4771. The examiner can normally be reached on Monday-Friday 5:30AM-3PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AARON ROANE/
Examiner, Art Unit 3739

/Roy D. Gibson/
Primary Examiner, Art Unit 3739